PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

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	Applicant's or agent's file reference P016626WO ZCW	FOR FURTHER ACTION	See Form PCT/IPEA/416				
	International application No. PCT/GB2005/000605	International filing date (day/mor 21.02.2005	priority date (day/month/year) 20.02.2004				
	International Patent Classification (IPC) or na INV. C07C233/68 C07C233/77 C07		167 A61K31/192 A61K31/216 A61K31/235				
	Applicant UCL BIOMEDICA Pic et al.						
This report is the international preliminary examination report, established by this International Preliminary Examinin Authority under Article 35 and transmitted to the applicant according to Article 36.							
	2. This REPORT consists of a total of	of 15 sheets, including this cov	er sheet.				
	3. This report is also accompanied by	y ANNEXES, comprising:					
	a. 🛛 sent to the applicant and to	the International Bureau) a to	al of 18 sheets, as follows:				
sheets of the description, claims and/or drawings which have been amended and are the basis of this re and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).							
		Authority considers contain an amendment that goes as filed, as indicated in item 4 of Box No. I and the					
b. (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s) sequence listing and/or tables related thereto, in celectronic form only, as indicated in the Supple Relating to Sequence Listing (see Section 802 of the Administrative Instructions).							
ا آ (This report contains indications rel	ating to the following items:					
	☐ Box No. I Basis of the repo	ort					
	☐ Box No. II Priority	•••					
		ent of opinion with regard to no	velty, inventive step and industrial applicability				
1	☐ Box No. IV Lack of unity of i		,,,,,,,,,,,,,,				
	Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement						
	Box No. VI Certain documer						
	☐ Box No. VII Certain defects i						
	☐ Box No. VIII Certain observat	ions on the international applic	ation				
	Date of submission of the demand	Date o	completion of this report				
	20.12.2005	07.07	.2006				
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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. PCT/GB2005/000605

	Box No. I Basis	of the repor	t		
1.	With regard to the language , this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.				
	which is the late of the late	anguage of a t nal search (und n of the interna	nslations from the original language into the following language, translation furnished for the purposes of: der Rules 12.3 and 23.1(b)) ational application (under Rule 12.4) examination (under Rules 55.2 and/or 55.3)		
2.	With regard to the elements* of the international application, this report is based on (replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):				
	Description, Pages	S			
	1-3, 6, 8-12, 15-21,	23-28, 31-62	as originally filed		
	4, 5, 5a, 7, 13, 14, 2	22, 29, 30, 63,	filed with telefax on 20.12.2005		
	Claims, Numbers				
	1-40		filed with telefax on 20.12.2005		
	Drawings, Sheets				
	1/3-3/3		as originally filed		
	☐ a sequence li	sting and <i>l</i> or a	ny related table(s) - see Supplemental Box Relating to Sequence Listing		
3.	The amendments have resulted in the cancellation of: ☐ the description, pages ☐ the claims, Nos. ☐ the drawings, sheets/figs ☐ the sequence listing (specify): ☐ any table(s) related to sequence listing (specify):				
4.	had not been mad Supplemental Box ☐ the descrip ☐ the claims ☐ the drawin ☐ the sequel	le, since they (Rule 70.2(c) otion, pages 4, Nos. 1-40 gs, sheets/figsnee listing (sp	,5,5a,7,13,14,22,29,30,63,64		
	* If item 4	applies, so	ome or all of these sheets may be marked "superseded."		

10/590064IAP12 Rec'd PCT/PT021 AUG 2006

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		x No. III Non-establishment o plicability	of op	inion with regard to novelty, inventive step and industrial		
1.	The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:					
		☐ the entire international application,				
	\boxtimes	Claims Nos. 37-41				
because:						
	the said international application, or the said claims Nos. 37-41 relate to the following subject matter does not require an international preliminary examination (specify):					
		see separate sheet				
	the description, claims or drawings (indicate particular elements below) or said claims Nos. are so uncl that no meaningful opinion could be formed (specify):					
		the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinio could be formed.				
		no international search report has been established for the said claims Nos.				
the nucleotide and/or amino acid sequence listing does not comply with the s C of the Administrative Instructions in that:						
		the written form		has not been furnished		
				does not comply with the standard		
		the computer readable form		has not been furnished		
				does not comply with the standard		
the tables related to the nucleotide and/or amino acid sequence listing, if in computer reada not comply with the technical requirements provided for in Annex C-bis of the Administrative						
		See separate sheet for further	detai	ls ·		

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: Claims

9,17-40, 41, 43,44

No: Claims

1-8,10-16,42

Inventive step (IS)

Yes: Claims

No: Claims

1-44

Industrial applicability (IA)

Yes: Claims

1-44

No: Claims

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item I

Basis of the report

This report is based in the application as originally filed. The reason therefore is that the amendments submitted by fax on 20.12.05 do not fulfil the requirements of Hules 19(2) and 34(2) b) PCT; the amendments in the proviso in claim 1 under (i) and (ii) have no basis in the application as filed and as this proviso does not only exclude specific compounds disclosed in documents which do not relate to the same activity as the present application but it is more general; such amendments go beyond the disclosure of the application as filed and are not allowed under Rules 19(2) and 34(2) PCT. Hence, this international preliminary report is based on the description and claims as originally filed.

It is noted that the objections on paragraphs 40, 41, 43 and 44 would have been overcome with the amendments on pages 7, 22, 29, 30, 63 and 64 in the description.

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 37-41 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

Re Item V

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Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

- D1: DATABASE CA [Online] CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US; OHSHIMA, ETSUO ET AL: "Synthesis and antiallergic activity of 11-(aminoalkylidene)-6,11- dihydrodibenz[b,e]oxepin derivatives" XP002333556 retrieved from STN Database accession no. 1992:255459
- D2: WO 2004/078180 A2 (GUILFORD PHARMACEUTICALS INC., USA) 16 September 2004 (2004-09-16)
- D3: WO 2004/074224 A1 (ASTRAZENECA AB, SWED.) 2 September 2004 (2004-09-

02)

- D4: DATABASE CA [Online] CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US; ISHIKAWA, TADAHIRO ET AL: "Insulation film materials, varnishes containing them, polyoxazole-based microporous films with low moisture absorption manufactured from them, and semiconductor devices using them" XP002333557 retrieved from STN Database accession no. 2004:19987
- D5: WO 03/106420 A1 (ASTRAZENECA A.B., SWED.) 24 December 2003 (2003-12-24)
- D6: WO 03/091204 A1 (GLAXO GROUP LIMITED, UK) 6 November 2003 (2003-11-06)
- D7: DATABASE CA [Online] CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US; OREN, JAKOB ET AL: "Photochemical studies. Part 31. Homoconjugated ketones with extended unsaturation: wavelength-selective, regioselective, diastereoselective, and enantiospecific photochemical transformations of methyl 7-oxospiro[5.5]undeca-1,3- and -2,4-diene-2-carboxylate" XP002333558 retrieved from STN Database accession no. 1993:580433
- D8: DATABASE CA [Online] CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US; BERGMAN, NILS AAKE ET AL: "Chemical stability of a prostacyclin analog due to the absence of intramolecular catalysis" XP002333559 retrieved from STN Database accession no. 1988:221428
- D9: DATABASE BEILSTEIN [Online] XP002333560 accession no. BRN 7478893
- D10: DATABASE BEILSTEIN [Online] XP002333561 accession no. BRN 7705788
- D11: DATABASE BEILSTEIN [Online] XP002333562 accession no. BRN 7704940
- D12: DATABASE BEILSTEIN [Online] XP002333563 accession no. BRN 7434441
- D13: DATABASE BEILSTEIN [Online] XP002333564 accession no. BRN 3414970
- D14: DATABASE BEILSTEIN [Online] XP002333565 accession no. BRN 2803986
- D15: DATABASE BEILSTEIN [Online] XP002333566 accession no. BRN 7478893
- D16: DATABASE BEILSTEIN [Online] XP002333567 accession no. BRN 2576796
- D17: DATABASE BEILSTEIN [Online] XP002333568 accession no. BRN 2093695
- D18: DATABASE BEILSTEIN [Online] XP002333569 accession no. BRN 4862361
- D19: DATABASE BEILSTEIN [Online] XP002333570 accession no. BRN 2720943
- D20: DATABASE BEILSTEIN [Online] XP002333571 accession no. BRN 2578485
- D21: DATABASE BEILSTEIN [Online] XP002333572 accession no. BRN 9028430
- D22: DATABASE BEILSTEIN [Online] XP002333573 accession no. BRN 8102389

D23:	DATABASE BEILSTEIN [Online] XP002333574 accession no. BRN 7884890
D24:	DATABASE BEILSTEIN [Online] XP002333575 accession no. BRN 7884829
D25:	DATABASE BEILSTEIN [Online] XP002333576 accession no. BRN 7595800
D26:	DATABASE BEILSTEIN [Online] XP002333577 accession no. BRN 7157925
D27:	DATABASE BEILSTEIN [Online] XP002333578 accession no. BRN 5989239
D28:	DATABASE BEILSTEIN [Online] XP002333579 accession no. BRN 4000587
D29:	DATABASE BEILSTEIN [Online] XP002333580 accession no. BRN 945016
D30:	DATABASE BEILSTEIN [Online] XP002333583 accession no. BRN 433087
D31:	DATABASE BEILSTEIN [Online] XP002333584 accession no. BRN 2381895
D32:	WO0016756

US5342971 D33:

D34: US2003/0191069

- The present application relates to compounds according to formulae (I), (Ia), (Ib); their 1. use in the preparation of medicaments for the treatment of muscular disorders/gastrointestinal disorders/the modulation of peripheral cannabinoid receptors; pharmaceutical compositions comprising them and their use in an assay for identifying modulators of cannabinoid receptor activity.
- D1 discloses compound with m:140439-65-2 which is novelty destroying for the subject-2. mater of claims 1, 3, 6-8, 11, 13-15 and 42.
- D2 discloses compounds with m:377731-28-7; 378242-26-3; 378242-27-4; 378242-49-0; 3. 378242-61-6; 378242-62-7; 378242-63-8; 378242-66-1; 378243-04-0; 378243-05-1; 378243-06-2; 378243-07-3; 378243-08-4; 378243-14-2;378243-15-3; 378243-16-4; 378243-17-5; 378243-18-6; 378243-19-7; 378243-20-0; 378243-21-1; 378243-22-2; 378243-24-4; 378243-25-5; 378243-26-6; 378243-28-8; 378243-29-9; 378243-30-2 378243-32-4; 378243-67-5; 378243-68-6; 378243-72-2; 378243-77-7; 378243-80-2; 378243-81-3; 475653-40-8; 378242-22-9 according to claims 1-6, 11, 13-16 and 42.
- D3 discloses compounds with rn: 749229-45-6; 749229-46-7; 749229-47-8; 4. 749229-48-9; 749229-74-1; 749229-75-2; 749229-76-3; 749223-15-6; 749229-61-6; 749229-62-7; 749229-63-8; 749229-64-9 according to claims 1-6, 11, 13-16 and 42.

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- 5. D4 discloses compound with rn:393543-03-8. This disclosure anticipates the subject-matter of claims 1-8, 11, 13-16 and 42.
- D5 discloses compounds with m:637300-47-1; 637300-70-0; 637300-71-1; 637300-74-4;
 637300-75-5; 637300-76-6; 637300-77-7; 637300-78-8; 637300-79-9; 637300-80-2;
 637300-81-3; 637300-82-4; 637300-85-7; 637300-90-4; 637301-08-7; 637300-99-3;
 637301-00-9. This disclosure anticipates the subject-matter of claims 1-6,11, 13-16 and 42.
- 7. D6 discloses compounds with m:620601-11-8; 620601-12-9; 620601-13-0; 620601-15-2; 620601-16-3; 620601-20-9; 620599-79-3; 620599-80-6; 620599-83-9; 620599-84-0. This disclosure anticipates the subject-matter of claims 1-8, 10, 11, 13-16 and 42.
- 8. D7 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1, 6, 7, 11, 13, 14 and 42.
- 9. D8 discloses compounds falling under formula (I) which anticipate the subject-mater of claims 1-9, 11, 13-16 and 42.
- 10. D9 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1-5, 7, 11, 14-16 and 42.
- 11. D10 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1-5, 7, 8, 11, 13-16 and 42.
- 12. D11 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1, 7, 11, 13, 15 and 42.
- 13. D12 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1,-5, 7, 11, 13, 14 and 42.
- 14. D13 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1-5, 7, 11, 13, 14 and 42.

- 15. D14 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1-5, 7, 11 and 42.
- 16. D15 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1-5, 7, 11, 15, 16 and 42.
- 17. D16 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1-5, 7, 11 and 42.
- 18. D17 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1-5, 11 and 42.
- 19. D18 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1-5, 11, 12, 14-16 and 42.
- 20. D19 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1, 3, 11, 12, 14, 15 and 42.
- 21. D20 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1-5, 11, 12, 14 and 42.
- 22. D21 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1-4, 6, 11 and 42.
- 23. D22 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1-6, 11, 13 and 42.
- 24. D23 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1-6, 11, 13 and 42.
- 25. D24 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1-6, 11, 13 and 42.
- 26. D25 discloses a compound falling under formula (I) which anticipates the subject-mater

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of claims 1-6, 13 and 42.

- 27. D26 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1-6, 11, 13, 14 and 42.
- 28. D27 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1-6, 11, 13 and 42.
- 29. D28 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1-6, 11, 13 and 42.
- 30. D29 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1-6, 12 and 42.
- 31. D30 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1-6, 11 and 42.
- 32. D31 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1-7, 11, 12, 14-16 and 42.
- 33. D32- D34 disclose cannabinoid receptors comprising an aromatic moiety attached to a carboxylic or to an amide moiety and to a polar functional group.

Novelty

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- 34. The subject-matter of claims 1-8, 10-16 and 42 is not novel in the sense of Art. 33(2) PCT.
- a. D1 discloses compound with rn:140439-65-2 which is novelty destroying for the subject-mater of claims 1, 3, 6-8, 11, 13-15 and 42.
- b. D4 discloses compound with rn:393543-03-8. This disclosure anticipates the subject-matter of claims 1-8, 11, 13-16 and 42, which is therefore not novel.

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- c. D5 discloses compounds with rn:637300-47-1; 637300-70-0; 637300-71-1; 637300-74-4; 637300-75-5; 637300-76-6; 637300-77-7; 637300-78-8; 637300-79-9; 637300-80-2; 637300-81-3; 637300-82-4; 637300-85-7; 637300-90-4; 637301-08-7; 637300-99-3; 637301-00-9. This disclosure anticipates the subject-matter of claims 1-6,11, 13-16 and 42, which is therefore not novel.
- d. D6 discloses compounds with rn:620601-11-8; 620601-12-9; 620601-13-0; 620601-15-2; 620601-16-3; 620601-20-9; 620599-79-3; 620599-80-6; 620599-83-9; 620599-84-0. This disclosure anticipates the subject-matter of claims 1-8, 10, 11, 13-16 and 42, which is therefore not novel.
- e. D7 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1, 6, 7, 11, 13, 14 and 42, which is therefore not novel.
- f. D8 discloses compounds falling under formula (I) which anticipate the subject-mater of claims 1-9, 11, 13-16 and 42, which is therefore not novel.
- g. D9 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1-5, 7, 11, 14-16 and 42, which is therefore not novel.
- h. D10 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1-5, 7, 8, 11, 13-16 and 42, which is therefore not novel.
- i. D11 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1, 7, 11, 13, 15 and 42, which is therefore not novel.
- j. D12 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1,-5, 7, 11, 13, 14 and 42, which is therefore not novel.
- k. D13 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1-5, 7, 11, 13, 14 and 42, which is therefore not novel.
- I. D14 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1-5, 7, 11 and 42, which is therefore not novel.

- D15 discloses a compound falling under formula (I) which anticipates the subject-mater m. of claims 1-5, 7, 11, 15, 16 and 42, which is therefore not novel.
- D16 discloses a compound falling under formula (I) which anticipates the subject-mater n. of claims 1-5, 7, 11 and 42, which is therefore not novel.
- Ο. D17 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1-5, 11 and 42, which is therefore not novel.
- D18 discloses a compound falling under formula (I) which anticipates the subject-mater p. of claims 1-5, 11, 12, 14-16 and 42, which is therefore not novel.
- D19 discloses a compound falling under formula (I) which anticipates the subject-mater q. of claims 1, 3, 11, 12, 14, 15 and 42, which is therefore not novel.
- D20 discloses a compound falling under formula (I) which anticipates the subject-mater r. of claims 1-5, 11, 12, 14 and 42, which is therefore not novel.
- D21 discloses a compound falling under formula (I) which anticipates the subject-mater s. of claims 1-4, 6, 11 and 42, which is therefore not novel.
- t. D22 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1-6, 11, 13 and 42, which is therefore not novel.
- D23 discloses a compound falling under formula (I) which anticipates the subject-mater u. of claims 1-6, 11, 13 and 42, which is therefore not novel.
- D24 discloses a compound falling under formula (I) which anticipates the subject-mater ٧. of claims 1-6, 11, 13 and 42, which is therefore not novel.
- D25 discloses a compound falling under formula (I) which anticipates the subject-mater W. of claims 1-6, 13 and 42, which is therefore not novel.
- D26 discloses a compound falling under formula (I) which anticipates the subject-mater Χ.

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- of claims 1-6, 11, 13, 14 and 42, which is therefore not novel.
- y. D27 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1-6, 11, 13 and 42, which is therefore not novel.
- z. D28 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1-6, 11, 13 and 42, which is therefore not novel.
- a'. D29 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1-6, 12 and 42, which is therefore not novel.
- b'. D30 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1-6, 11 and 42, which is therefore not novel.
- c'. D31 discloses a compound falling under formula (I) which anticipates the subject-mater of claims 1-7, 11, 12, 14-16 and 42, which is therefore not novel.
 - Inventive step
- 35. The subject-matter of claims 9, 17-41, 43 and 44 does not involve an inventive step in the sense of Art. 33(3) PCT.
- a. Modulators of cannabinoid receptors with a structure comprising an aromatic ring attached to a carboxylic or amide moiety and with another polar moiety in the structure are known in the art (D32-D34).
- b. The provision of further compounds with the same technical features in the structure and with the same activity would be obvious for the skilled person in the art. Furthermore, activity data has only been provided for one single compound, compound 16. Inventive step could only be acknowledged if activity data are provided for a broader scope of compounds and the scope of the protection is restricted to compounds covered by the technical features in the formula of the tested compounds provided showing an unexpected effect such as improved aqueous solubility and/or decreased lipophilicity (as reported on page 5 of the description) over known cannabinoid receptor modulators

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(comparative examples). As such an evidence of improvement over the prior art and activity data which covers a reasonable scope of the protection are not available at the moment, inventive step cannot be acknowledged.

Further comments

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- 36. Documents D2 and D3 could become very relevant to assess the patentability of the present application when it enters the national/regional phase. No check has been carried out whether the priority dates of the present application and D2 and D3 have been validly claimed.
- 37. For the assessment of the present claims 37-41 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.
- 38. The same formula is named (I) in claim 1 but (Ia) in claims 20, 22 and 23, leading therefore to lack of clarity, contrary to Art. 6 PCT.
- 39. There is a typing mistake in claim 9.
- 40. The expression "the contents of which are incorporated herein by reference" used in the description renders unclear the scope of the protection sought, contrary to Art. 6 PCT.
- 41. The use of the terms "and the like" in the description renders unclear the scope of the protection sought, contrary to Art. 6 PCT.
- 42. The use of the word "approximately" in the description renders unclear the scope of the protection sought, contrary to Art. 6 PCT.
- 43. The passages on page 29 from line 24 to 32 renders unclear the scope of the protection

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sought, contrary to Art. 6 PCT. The skilled person in the art would not know which specific compounds fall within the scope of the protection, contrary to Art. 6 PCT. These passages should not have been included in the description.

- 44. The last paragraph in the description is vague and ambiguous rendering therefore unclear the scope of the protection sought, contrary to Art. 6 PCT.
- 45. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D32-D34 is not mentioned in the description, nor are these documents identified therein.